IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA,	:	
Plaintiffs,	:	
	:	C.A. No. 10-915-LPS
v.	:	**FILED UNDER SEAL**
WATSON LABORATORIES, INC. (NV) and EGIS PHARMACEUTICALS PLC,	:	
Defendants.	:	

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MEMORANDUM OPINION

November 14, 2012
Wilmington, Delaware

STARK, U.S. District Judge:

Presently before the Court are Defendants' motion to exclude Plaintiffs' legal expert (D.I. 343) and Defendants' motion to exclude Plaintiffs' expert testimony on state of mind (D.I. 341). For the reasons discussed below, the Court will grant Defendants' motion to exclude Plaintiffs' legal expert and grant in part and deny in part Defendants' motion to exclude Plaintiffs' expert testimony on state of mind.

I. BACKGROUND

On October 26, 2010, Plaintiffs AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively, "Plaintiffs") filed a complaint alleging that New Drug Application No. 202172, filed by Defendant Watson Laboratories, Inc. (NV) ("Watson"), infringes Plaintiffs' U.S. Patent No. RE37, 314 (the "'314 patent" or "patent-in-suit"). (D.I. 1) On November 23, 2011, Plaintiffs filed their Second Amended Complaint, which added claims against Egis Pharmaceuticals PLC (together with Watson hereinafter referred to as "Defendants"). (D.I. 110) Trial is set to begin on December 12, 2012.

II. LEGAL STANDARDS

The admissibility of expert testimony is a question of law governed by Rule 702 of the Federal Rules of Evidence. *See Daubert v. Merrell Dow Pharms.*, 113 S. Ct. 2786 (1993). Under Rule 702, "(1) the proffered witness must be an expert; (2) the expert must testify to scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact." *United States v. Velasquez*, 64 F.3d 844, 849 (3d Cir. 1995). The admissibility of expert testimony is within the discretion of the Court. *See Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008). The Court serves as a gatekeeper ensuring that evidence is relevant and

reliable. *See id.*

III. DISCUSSION

A. Legal Expert

Plaintiffs propose to offer at trial the testimony of a legal expert, William F. Smith. Mr. Smith is an attorney and former PTO examiner and Special Program Examiner as well as a former Administrative Patent Judge on the Board of Patent Appeals and Interferences. (D.I. 351 at 5-6) He is not, however, a person of ordinary skill in the art of the patent-in-suit. Plaintiffs claim that Mr. Smith will assist "the Court's understanding that an experienced chemical patent practitioner would read neither the patent's claims nor prosecution history as affirmatively limiting the patent's description of the rosuvastatin invention and the scope of the salts that are equivalent." (D.I. 350 at 1-2) Plaintiffs also seek to offer Mr. Smith's testimony on the topics of whether the patent-in-suit teaches away from rosuvastatin zinc or other equivalents and whether Egis will likely obtain a patent on rosuvastatin zinc. (*Id.*)

As Defendants emphasize, the judges in this District have a well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances. *See, e.g.*, *Brigham & Women's Hosp. Inc. v. Teva Phams. USA, Inc.*, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010) (Bartle, J.) ("[T]he law in this district is clear that experts may not opine on . . . substantive issues of patent law . . . [or] explain patent prosecution histories through expert testimony . . . ."); *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 2009 WL 2913615, at ¶ 1 (D. Del. Mar. 4, 2009) (striking various legal experts); D.I. 344 Ex. 2 (Judge Robinson's "Additional Civil Trial Guidelines for Patent Cases") ("[E]xpert testimony from attorneys regarding patent practice and procedure is not required and will not be permitted except for extraordinary circumstances.

'Expert' legal testimony (as opposed to technical testimony) on such substantive issues as invalidity (by anticipation, obviousness, on-sale bar, prior conception, etc.) and claim construction and infringement, generally is not admitted, as descriptions of the law and instructions on the law are matters for the court."); *see also Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1364 (Fed. Cir. 2008) (finding abuse of discretion in denying motion to exclude testimony of legal expert, as such expert should not be permitted to testify on issues "such as the nature of the claimed invention, what a prior art reference discloses, or whether the asserted claims read on the prior art reference").

The Court sees no reason to depart from this practice in the circumstances presented by the instant case. Under the circumstances presented here, Mr. Smith's testimony (including on procedures at the PTO) will not be helpful to the Court. Accordingly, Defendants' motion to exclude the testimony of Plaintiffs' legal expert will be granted.

B. Expert Testimony on State of Mind

Plaintiffs also propose to offer at trial the expert testimony of Dr. William R. Roush, "a preeminent chemist with over thirty years of experience in the fields of organic and medicinal chemistry." (D.I. 351 at 5) Defendants contend that at least portions of Dr. Roush's intended testimony is inadmissible state of mind testimony.[1] Defendants focus their motion on Dr. Roush's testimony opining on what the inventors of the '314 patent "knew" and "considered" regarding the disclosure of zinc in the prior art. (D.I. 299 ¶ 118) Defendants also object to Dr.

[1]Defendants also seek to exclude testimony of Plaintiffs' legal expert, Mr. Smith, as improper state of mind testimony. As the Court is excluding the entirety of Mr. Smith's testimony, it is not necessary to deal with the state of mind issue in connection with Mr. Smith.

Roush's testimony related to what Shionogi as a company "knew" about statins containing a zinc cation. (D.I. 352 Ex. 2 ¶ 22) Plaintiffs respond that Dr. Roush's expert testimony does touch on any inventor's subjective state of mind. Rather, in Plaintiffs' view, Dr. Roush addresses how one of ordinary skill in the art would read and interpret the '314 patent.

Generally, "expert witnesses are not permitted to testify regarding 'intent, motive, or state or mind, or evidence by which such state of mind may be inferred.'" *In re Rosuvastatin Calcium Patent Litig.*, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) (quoting *Oxford Gene Tech., Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 443 (D. Del. 2004)). The two portions of Dr. Roush's testimony highlighted by Defendants constitute expert testimony regarding state of mind and, therefore, will be excluded. At paragraph 118 of his expert report, Dr. Roush opines that "it is not reasonable to infer that the '314 patent inventors knew[] of zinc from within the broad list of counterions of the '784 Merck patent." (D.I. 299 ¶ 118) At paragraph 22 of his reply expert report, Dr. Roush opines that "the '039 patent is completely irrelevant to whether Shionogi knew of pharmaceutically acceptable salts of statins containing a zinc cation." (D.I. 352 Ex. 2 ¶ 22) Dr. Roush will not be permitted to testify as to what the inventors, or Shionogi, knew or intended.

However, to the extent Defendants are seeking to exclude Dr. Roush's testimony as to what one of ordinary skill in the art would understand about rosuvastatin zinc or other zinc salts in the context of the patent-in-suit, Defendants' motion will be denied. So long as Dr. Roush's focus is on what one of ordinary skill in the art would understand – and not on what the inventors or Shionogi knew or intended – Dr. Roush's testimony will be permitted. (D.I. 351 at 12) ("Dr. Roush focuses on the perception of a person of skill in the art rather than the inventor.")

Accordingly, Defendants' motion will be granted in part and denied in part.

IV. CONCLUSION

An appropriate Order follows.